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QUESTIONS EXTRACTED FROM TTB NOTICE No 41 published 29.4.05 ref

Re: Advance notice of proposed rulemaking (ANPRM) on Labelling and Advertising for Alcoholic Beverages

General (p22275)

- 01. Should TTB require mandatory nutrition labelling (ie calories, fat, carbohydrates, & protein) or should nutrition information be permitted only on a voluntary basis?
- A1. Nutrition labelling should be on a voluntary basis.
- Q2. Should TTB require mandatory ingredient labelling (i.e. a list of all ingredients used to make the product including processing aids) or should ingredient labelling be permitted only on a **voluntary** basis?
- A2. Listing initial ingredients/raw materials including processing aids would be misleading to consumers of spirit drinks because of their transformation in the manufacturing process and/or absence in the final product.
- O3. What areas need further research and evaluation before TTB can reach decisions on whether and how changes can be made?
- *A3*. The labelling and advertising matters raised in the Bureau's advance notice would not appear to be issues that require further research and evaluation.
- O4. Are there modifications TTB can make to current requirements regarding alcoholic beverage labels to help consumers better understand and benefit from the information on the label?
- For spirits (HS 2208) current TTB labelling requirements convey key product A4. information, such as class and type of product, trader's details, alcoholic strength, liquid content and caution against excessive consumption, in a clear manner. See also the answers to Question 7 below, and 'Alcohol Facts' section Question 5.

- Q5. Should TTB harmonise its alcohol beverage labelling regulatory requirements with those of other major producing nations, eg EU Member States, Australia & Canada, and with regulatory schemes of other Federal agencies, eg Food & Drug Administration (FDA)? If so, how would that be best done?
- A5. A consistent approach between trading partners is in principle desirable.
- Q6. Are consumers likely to derive benefits from more specific information on alcohol beverage labels, and, if so, are those benefits sufficient to warrant the economic costs associated with such revisions?
- A6. It would be beneficial to consumers if (a) a statement of alcoholic strength and (b) where relevant, an allergen statement were required on all alcoholic beverages.
- Q7. What should be the TTB's priorities in deciding which changes to make on alcohol beverage labels, ie which changes are most important and which are least important?
- A7. The most important changes for TTB to make on alcohol beverage labels are:
 - Alcoholic strength required on all alcoholic beverages
 - Allergen labelling, when necessary

It would also be helpful if "Serving Facts" were permitted on a voluntary basis on all alcoholic drinks.

- Q8. Should any new labelling requirements apply equally to advertisements?
- A8. No.

A. Calorie and Carbohydrate Claims (p22278)

- A Q1. Should TTB promulgate regulations that define "low carbohydrate" as containing no more than 7 grams of carbohydrates per standard serving size, as specified in TTB Ruling 2004-1? Why or why not?
- A A1. See Q&A No.3 below
- A Q2. Should TTB continue to prohibit use of the terms "effective carbohydrates" and "net carbohydrates" on labels and in advertisements? Why or why not?
- A A2. Yes. Further qualification of carbohydrate content is potentially confusing and would require elaborate rules to ensure their correct usage.
- A Q3. Should TTB wait for the conclusion of FDA's regulatory decision-making process for use of the term "low carbohydrate" for food and beverage products [that] FDA regulates before issuing regulations on a low carbohydrate standard for alcohol beverage products?
- A A3. Yes, consistency between FDA and TTB Standards would help the consumer. Until FDA finalizes its position, TTB should abide by its position as set forth in TTB Ruling 2004-1.

- A Q4. How should TTB define the terms "low calorie" and "reduced calorie"? Should it propose standards for these claims consistent with FDA standards? Should TTB develop its own alternate set of standards and, if so, what should they be?
- A A4. Any proposed TTB standards for "low calorie" and "reduced calorie" claims should be consistent with FDA standards to avoid consumer confusion.
- A Q5. Should TTB establish regulations for use of the terms "light" and "lite"? If so, should it propose standards for these claims consistent with FDA standards? How would these standards apply to products for which the term "light" is part of the identity standard (eg "light whisky" [emphasis added] or "light wine")?
- A A5. The description of "light" or "lite" is confusing for consumers because it does not have a consistent meaning. The use of "light" or "lite" for beers means that it is low alcohol, for most foodstuff it means low calorie, whereas under US regulations for "whisky" it means the product is distilled at over 160 degrees proof (as distinct from under 190 degrees proof). The industry believes this definition of the term "light" or "lite" when used on "whisky" is not likely to be known to consumers, and furthermore "light whisky" and all other "whisky" are required to have the same minimum bottling strength anyway.

B. Petition for "Alcohol Facts" Label and Ingredient Labelling (p22280)

- B Q1. Should alcohol beverage containers bear an Alcohol Facts label similar to the one presented in the Centre for Science in the Public Interest (CSPI) petition? Why or why not?
- B A1. The presentation of the information in the Alcohol Facts label in the CSPI petition, particularly the ingredient statement, is likely to confuse the consumer. A possible voluntary 'Serving Facts' label (see section D below) would appear more meaningful to consumers.
- B Q2. Should such a label include an ingredient list as suggested in the CSPI petition?
- B A2. No. The definition of the product, in accordance with TTB standards of Identity, together with the alcoholic strength, should be sufficient to inform the consumer of the nature of the product. See also response preceding question, and to 'General' section Question 2 above.
- B Q3. Should the label be voluntary or mandatory?
- B A3. The label is not considered appropriate (see also Question 1 above), but a declaration of alcoholic strength should become mandatory for all alcoholic drinks (see also Question B.5 below).
- B Q4. If mandatory, should there be any exemptions from the alcohol facts and ingredient labels, eg for small businesses or for small containers?
- B A4. It should not be mandatory but, if it were, yes. Consideration should be given to establish a minimum threshold for sizes of small containers to be exempt.
- B Q5. Should current alcohol content statement labelling requirements be expanded to cover wines with of 14 % alc by vol or less and malt beverages?

- B A5. Yes, definitely. All alcoholic beverages should be required to declare their alcoholic strength. Knowing the alcohol content of a product a consumer chooses to purchase is a critical fact in drinking responsibly.
- B Q6. What would be the costs associated with mandatory alcohol facts and ingredient labelling to the industry and, ultimately, the consumer?
- B A6. Costs would involve designing new labels, printing one or more additional labels, resetting of bottling and labelling machinery, which may therefore be substantial.
- B Q7. How might consumers benefit from such a label?
- B A7. Notwithstanding the reservations about such a label (see responses to Q1 and Q2 above), consumers would benefit from all alcoholic beverages being required to declare their alcoholic strength (%vol). See also answer to Q5 above.
- B Q8. As a consumer, how much extra would you be willing to pay for alcohol facts and ingredient labelling information?
- B A8. --
- B Q9. Are there alternatives to mandatory alcohol facts and ingredient labelling? Eg, if a label lists a website or telephone number where a consumer could obtain such information about the product, would this be sufficient?
- B A9 Yes. Point of sale information, provision of a website or point of contact for additional product information would inform those who wish to know specific details about a particular product.

C. Allergen Labelling (p22280/1)

- C Q1. Should TTB require allergen labelling on alcohol beverage containers to be part of or adjacent to a larger list of all ingredients found in the product, similar to the requirements of the Food Allergen Labelling and Consumer Protection Act of 2004? Why or why not?
- C A1. Consistent with the EU approach, a separate allergen labelling declaration should only be required if the allergen present in the final product is not identified in the product name or elsewhere on the label.
- C Q2. If the product name on the label of an alcohol beverage container indicates that an allergen is present in the product, is it helpful to the consumer to have the allergen labelled again in a standardized allergen statement elsewhere on the container? Eg, if a product is called "Wheat Beer", should it also have a label elsewhere on the container reading "Allergens: wheat"? Why or why not?
- C A2. It should be sufficient for the allergen to appear in the product name.
- C Q3. TTB's current regulations allow certain allergens such as milk, albumen (egg), isinglass (a protein from fish bladders) and soy flour to be used as fining, processing, and filtering agents in the production of alcohol beverages. While fining, processing, and filtering agents are not primary ingredients in an alcohol beverage product, low levels of

- an agent may remain in the final product after production. When an allergen is used as a fining, processing, or filtering agent to produce an alcohol beverage, should TTB require that the product be labelled "Processed with [a specific allergen]" or "May contain [a specific allergen]"? Why or why not?
- C A3. When an allergen is used as a fining, processing or filtering agent to produce a beverage alcohol product, the finished product will require allergen labelling pursuant to the Food Allergen Labelling and Consumer Protection Act if the allergenic protein remains in the finished product and poses a risk to human health. See also response to Question 5 below.
- C Q4. Should allergenic fining, processing, and filtering agents be labelled in the exact same fashion as all other allergen ingredients? Why or why not?
- C A4. These should be dealt with in the same way as other allergenic ingredients. The determinant for a necessary label declaration should be whether an allergen is present in the final product. See also response to Question 3 above.
- C Q5. Testing methods for detecting allergens in food and beverage products typically can only detect an allergen if it is present at or above a certain minimum value. Accordingly, would it be helpful to consumers for TTB to require an allergenic fining, processing, or filtering agent to be labelled regardless of whether a detection test shows that the allergen is or is not present in the final product? Why or why not?
- C A5. Consistent with the EU approach, if it can be shown that the process of manufacture of the processing aid or subsequent procedures in its use have removed the allergenic protein, there should be no need for an allergen warning on the label. See also response to Question 3 above.
 - The use of allergen warning labels in cases of possible presence of allergens in the final product (e.g. "may contain") has been shown to unnecessarily restrict consumer choice, to undermine consumer's trust in the reliability of such labelling when an allergen is present, and to lead to complacency about heeding warning labels with potential harmful consequences for consumers' health.
- C Q6. What is the lowest amount of an offending food allergen (or minimum threshold level) in an alcohol beverage product necessary to provide a mild, yet perceptible adverse allergic reaction in consumers with the most sensitive food allergies?
- C A6. CEPS is aware that data on levels of allergens that have been reported to trigger allergic reactions have been reviewed by the European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA). The EU spirits industry would welcome a harmonised approach to allergen labelling between the US and Europe so that consumers can have confidence in allergen labelling. TTB should take its lead from FDA and EFSA when considering these aspects of allergen labelling.
- C Q7. Is it possible to define a minimum threshold level for each major food allergen? If so, what are the minimum threshold levels for each major food allergen?
- C A7. Again, this is a complex area which can only be answered by in-depth objective scientific analysis. See response to Q6 above.

- C Q8. If FDA and/or the scientific community establish conclusively a minimum threshold level for a particular allergen, should TTB exempt from any allergen labelling requirements products containing the allergen proteins, but at a level below the established minimum threshold level?
- C A8. This is a complex area. See response to Q6 above.
- C Q9. What would be the costs associated with mandatory allergen labelling to the industry and, ultimately, the consumer?
- C A9. --
- C Q10. How might consumers benefit from allergen labelling?
- C A10. Consumers with an allergy or potential allergy would be better informed and consequently better able to protect themselves against any risk from a product that might cause an allergic reaction.

The vast majority of distilled alcoholic beverages are free of proteins and therefore free from substances that may cause an allergic reaction. This would become clear to consumers from the absence of allergen labelling on them.

D. Requests for Voluntary "Serving Facts" Labelling (p22282)

- D Q1. Should alcohol beverage containers bear a Serving Facts label similar to the one presented (see p22281/2)? Why or why not?
- DA1. Any inclusion of a Serving Facts label should be on a voluntary basis. A standard format would ensure consistency of presentation and facilitate assimilation of the information therein.
- D Q2. Should such a label include a definition of a "standard drink" and if so, how should a "standard drink" be defined?
- DA2. The US definition of a "standard drink" already exists (viz 12oz of regular beer=1½oz of spirits=5oz of wine, each containing 0.6 oz of alcohol). An option to include such information in the "Serving Facts" label should be permitted.
- D Q3. Should such a label include graphic icons similar to, but not necessarily limited to, the one presented (see p22281)? Why or why not?
- D A3. Yes. The industry supports the proposed voluntary alcohol equivalency logo.
- D Q4. Should the label be voluntary or mandatory?
- D A4. It should be on a voluntary basis.
- D Q5. If mandatory, should there be any exemptions from the serving facts label, such as for small businesses or for small containers?
- D A5. It should not be mandatory but, if it were, consideration should be given to establishing a minimum threshold for sizes of small containers to be exempt.

- D Q6. If not mandatory for all alcohol beverage products, should the Serving Facts label be required at least on alcohol beverages that make certain calorie or carbohydrate claims?
- D A6. Where a voluntary claim is made, mandatory inclusion of a Serving Facts label would be acceptable.
- D Q7. What would be the costs associated with mandatory serving facts labelling to the industry and, ultimately, the consumer?
- D A7. Costs would involve designing new labels, printing one or more additional labels, resetting of bottling and labelling machinery, which may therefore be significant.
- D Q8. How might consumers benefit from such a label?
- D A8. The consumer will determine the value and benefits of such a label.
- D Q9. As a consumer, how much extra would you be willing to pay for serving facts labelling information?
- D A9. --
- D Q10. Are there alternatives to mandatory serving facts labelling? Eg, if a label lists a website or telephone number where a consumer could obtain such information about the product, would this be sufficient?
- D A10. Yes. Point of sale information, provision of a website or point of contact for additional product information would inform those who wish to know specific details about a particular product.
- D Q11. Should TTB allow a further breakdown of nutrients (eg, trans fat, sugars, fibre)?
- D A11. CEPS does not believe this is appropriate for alcoholic beverages.
- D Q12.Does the use of "standard drink" and "serving size" on the same label create confusion? Does any confusion arise if a label specifies ounces of alcohol in conjunction with serving size and percent alcohol?
- D A12. The provision of clear information to consumers allows them to make informed decisions about appropriate consumption. Use of these two concepts on the same label should not be confusing. Neither should the inclusion of ounces of alcohol be problematic.

E. Composite Label Approach (p22282)

- E Q1. Would a composite label, which combines the essential information on the examples discussed (see ANPRM), be appropriate to provide the consumer with information they want and need to see on alcohol beverage product labels?
- E A1. See response to Question B.1 above.
- E Q2. Should such a composite label be mandatory or voluntary?
- E A2. See response to Question B.1 above.